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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624,389

07/22/2003

Mark C. Estes

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6826

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EXAMINER

DESANTO, MATTHEW F

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/624,389	Applicant(s) ESTES ET AL.	
	Examiner MATTHEW F. DESANTO	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-74 is/are pending in the application.
4a) Of the above claim(s) 35-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>Multiple IDS from 6/12/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 10-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (US 20030060765) as applied to claims cited in the office action dated 3/7/07, and further in view of Galley et al. (USPN 6,544,212).

3. Campbell et al. discloses an infusion device with a characteristic determining device and an infusing device as well as all the particulars of the claims except for a program that determines the analyte levels over time and recalculates the delivery profile in accordance with the levels of analyte.

4. Gallery et al. discloses a system for providing glycemic control that has a processor that deals with conducting glucose measurements and the using the processor to what the future glucose levels will be as well as measuring the glucose levels over time and then determining the delivery profile based on the readings and algorithm (entire reference). Gallery et al. discloses two algorithms that include a feedback algorithm and a feedforward algorithm, which determined the infusion rate. The infusion rate is only determined after results of the algorithm and thus wouldn't be calculated if the glucose levels were within there proper range.

5. At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Campbell et al. with the teachings of Gallery et al. because Gallery et al. discloses a more effective treatment method for diabetes because of the constant feedback provided by the algorithms.

6. Claims 1-6, 10-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes et al. (US 20030114836) as applied to claims cited in the office action dated 3/7/07, and further in view of Galley et al. (USPN 6,544,212).

7. Estes et al. discloses an infusion device with a characteristic determining device and an infusing device as well as all the particulars of the claims except for a program that determines the analyte levels over time and recalculates the delivery profile in accordance with the levels of analyte.

8. Gallery et al. discloses a system for providing glycemic control that has a processor that deals with conducting glucose measurements and the using the processor to what the future glucose levels will be as well as measuring the glucose levels over time and then determining the delivery profile based on the readings and algorithm (entire reference). Gallery et al. discloses two algorithms that include a feedback algorithm and a feedforward algorithm, which determined the infusion rate. The infusion rate is only determined after results of the algorithm and thus wouldn't be calculated if the glucose levels were within there proper range.

9. At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Estes et al. with the teachings of Gallery et al. because

Gallery et al. discloses a more effective treatment method for diabetes because of the constant feedback provided by the algorithms.

Response to Arguments

10. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

11. The previous rejection has been withdrawn.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
/Matthew F DeSanto/
Primary Examiner, Art Unit 3763